US010406291B2

(12) **United States Patent**
Hansen et al.

(10) **Patent No.: US 10,406,291 B2**
(45) **Date of Patent: Sep. 10, 2019**

(54) **AUTOINJECTOR HAVING NEEDLE SHIELD TRIGGERING**

(71) Applicant: **Novo Nordisk A/S**, Bagsvaerd (DK)

(72) Inventors: **Soeren Kjellerup Hansen**, Fjenneslev (DK); **Mads Schenstroem Stefansen**, Copenhagen OE (DK); **Matias Melander**, Copenhagen (DK); **Bastian Gaardsvig Kjeldsen**, Hilleroed (DK)

(73) Assignee: **Novo Nordisk A/S**, Bagsvaerd (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 33 days.

(21) Appl. No.: **15/301,108**

(22) PCT Filed: **Apr. 7, 2015**

(86) PCT No.: **PCT/EP2015/057526**
§ 371 (c)(1),
(2) Date: **Sep. 30, 2016**

(87) PCT Pub. No.: **WO2015/150578**
PCT Pub. Date: **Oct. 8, 2015**

(65) **Prior Publication Data**

US 2017/0014575 A1 Jan. 19, 2017

(30) **Foreign Application Priority Data**

Apr. 4, 2014 (EP) 14163586

(51) **Int. Cl.**
A61M 5/20 (2006.01)
A61M 5/315 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 5/31501*** (2013.01); ***A61M 5/20*** (2013.01); ***A61M 5/24*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 5/31501; A61M 5/20; A61M 5/24; A61M 5/31585; A61M 5/3234;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,752,918 A 7/1956 Uytenbogaar
5,658,259 A 8/1997 Pearson et al.
(Continued)

FOREIGN PATENT DOCUMENTS

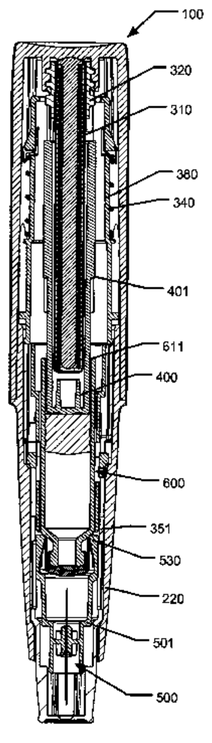
WO 94/07553 A1 4/1994
WO 02/17996 A1 3/2002
(Continued)

Primary Examiner — Bradley J Osinski
Assistant Examiner — Nilay J Shah
(74) *Attorney, Agent, or Firm* — Wesley Nicolas

(57) **ABSTRACT**

An autoinjector (**100**) for expelling a single dose of drug from a drug cartridge (**600**) including a piston (**630**), the autoinjector including: a base (**200**, **220**), a needle (**500**) that is fixedly mounted relative to the base (**200**, **220**), a plunger (**310**, **320**, **400**) adapted for cooperation with the piston (**630**), an actuating spring (**330**) provided as a helical compression spring arranged to act on the plunger (**310**, **320**, **400**) by exerting an axial force on the plunger to drive the piston (**630**) distally, and a needle shield (**350**, **380**) axially movable relative to the base (**200**, **220**) between an extended position and a collapsed position. The autoinjector defines a lock (**320**, **328**, **380**, **388**) that is released when the needle shield (**350**, **380**) is moved from the extended position to the collapsed position. The lock (**320**, **328**, **380**, **388**) releases to enable relative rotation between plunger thread (**325**) and base thread (**205**) causing release of the plunger (**310**, **320**, **400**) from the initial axial position and expelling the dose of the drug.

11 Claims, 7 Drawing Sheets



(51) **Int. Cl.**
A61M 5/32 (2006.01)
A61M 5/24 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 5/31585*** (2013.01); ***A61M 5/3234*** (2013.01); ***A61M 5/3243*** (2013.01); *A61M 5/31565* (2013.01); *A61M 5/31583* (2013.01); *A61M 2005/2013* (2013.01); *A61M 2005/247* (2013.01); *A61M 2005/2433* (2013.01); *A61M 2005/3247* (2013.01)

(58) **Field of Classification Search**
CPC A61M 5/3243; A61M 5/31565; A61M 5/31583; A61M 5/3159; A61M 5/31591; A61M 5/3232; A61M 5/3245; A61M 5/3257; A61M 5/326; A61M 5/31571; A61M 2005/2013; A61M 2005/2433; A61M 2005/247; A61M 2005/3247
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,210,369	B1	4/2001	Wilmot et al.	
6,743,203	B1	6/2004	Pickhard	
7,449,012	B2	11/2008	Young et al.	
7,717,877	B2	5/2010	Lavi et al.	
8,409,141	B2	4/2013	Johansen et al.	
2005/0261634	A1*	11/2005	Karlsson	A61M 5/20 604/197
2013/0018313	A1	1/2013	Kramer et al.	
2013/0274668	A1*	10/2013	Barrow-Williams	A61M 5/2033 604/136
2013/0274676	A1	10/2013	Ekman et al.	

FOREIGN PATENT DOCUMENTS

WO	02/053214	A1	7/2002
WO	2004/028598	A1	4/2004
WO	2006/130098	A1	12/2006
WO	2008/116688	A1	10/2008
WO	2008116766	A1	10/2008
WO	2011/012903	A1	2/2011
WO	2011/101377	A1	8/2011
WO	2011/101382	A1	8/2011
WO	2011/111006	A2	9/2011
WO	2012/022810	A2	2/2012
WO	2012/085025	A1	6/2012
WO	2012/122643	A1	9/2012
WO	2012/173553	A1	12/2012
WO	2013/012745	A1	1/2013
WO	2014001319	A1	1/2014

* cited by examiner

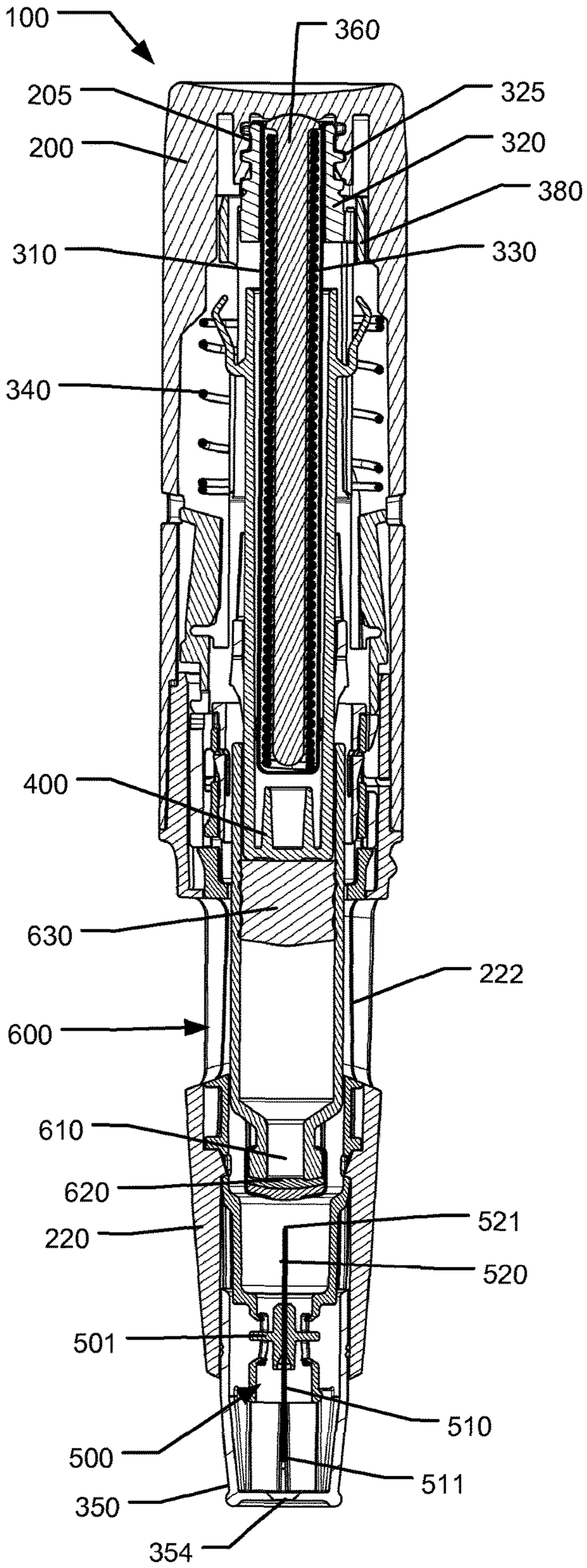

100
360
205
325
200
320
380
310
330
340
400
630
222
600
610
620
220
521
520
501
510
500
511
350
354

Fig. 1a

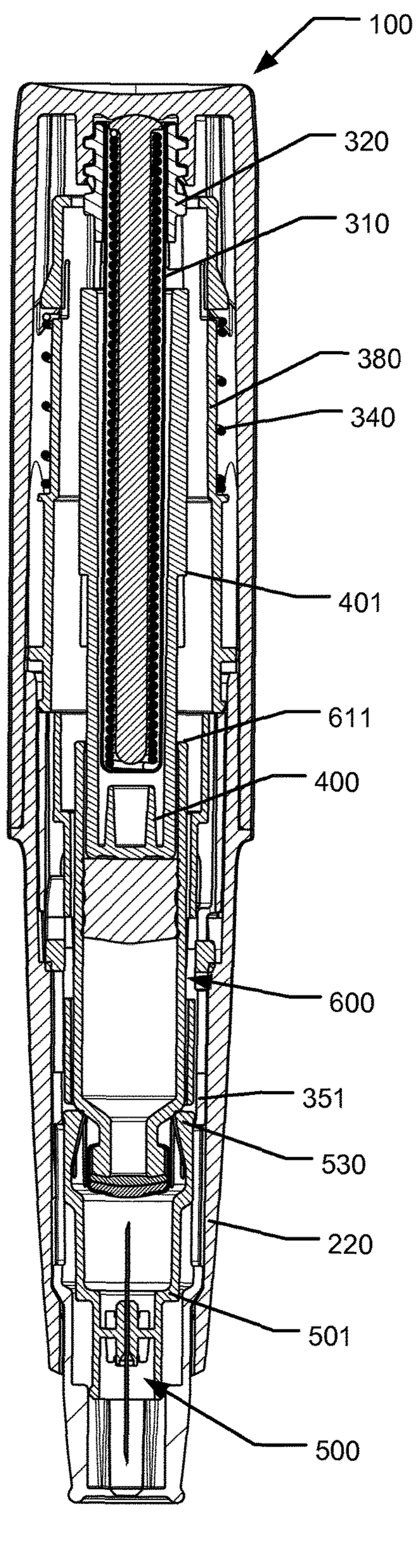

100
320
310
380
340
401
611
400
600
351
530
220
501
500

Fig. 1b

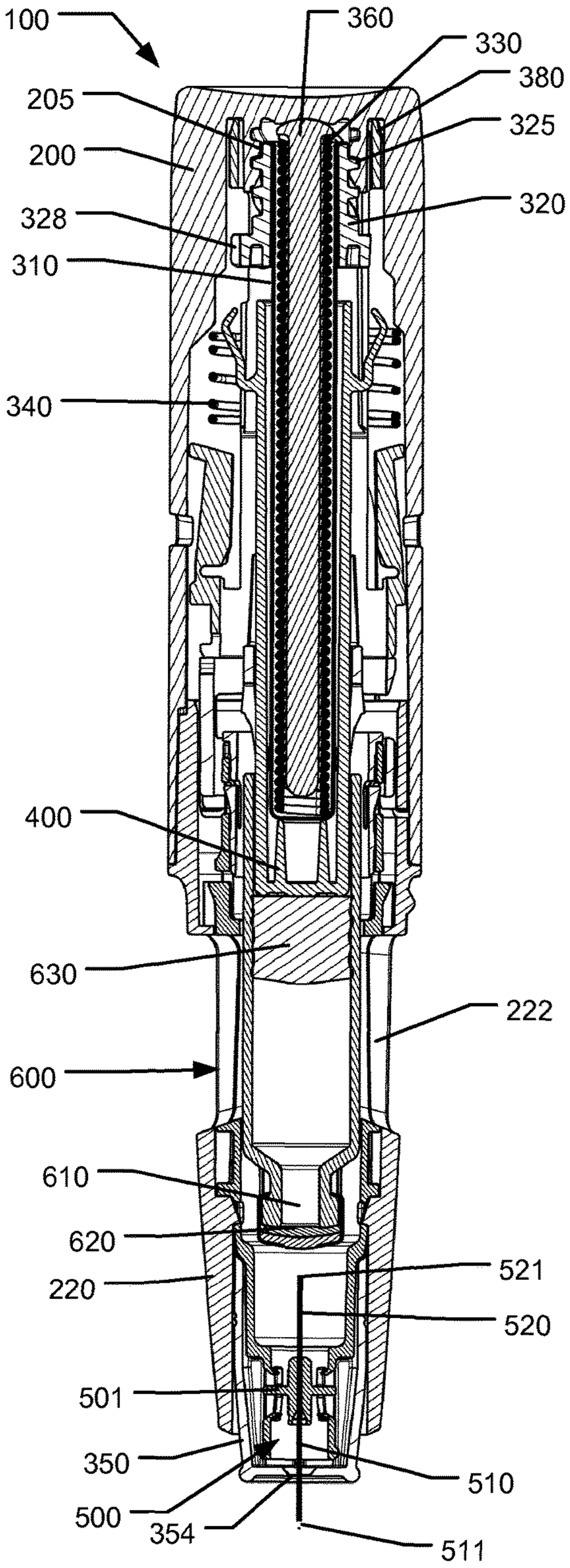

100
360
330
380
205
325
200
320
328
310
340
400
630
222
600
610
620
521
220
520
501
350
510
500
354
511

Fig. 2a

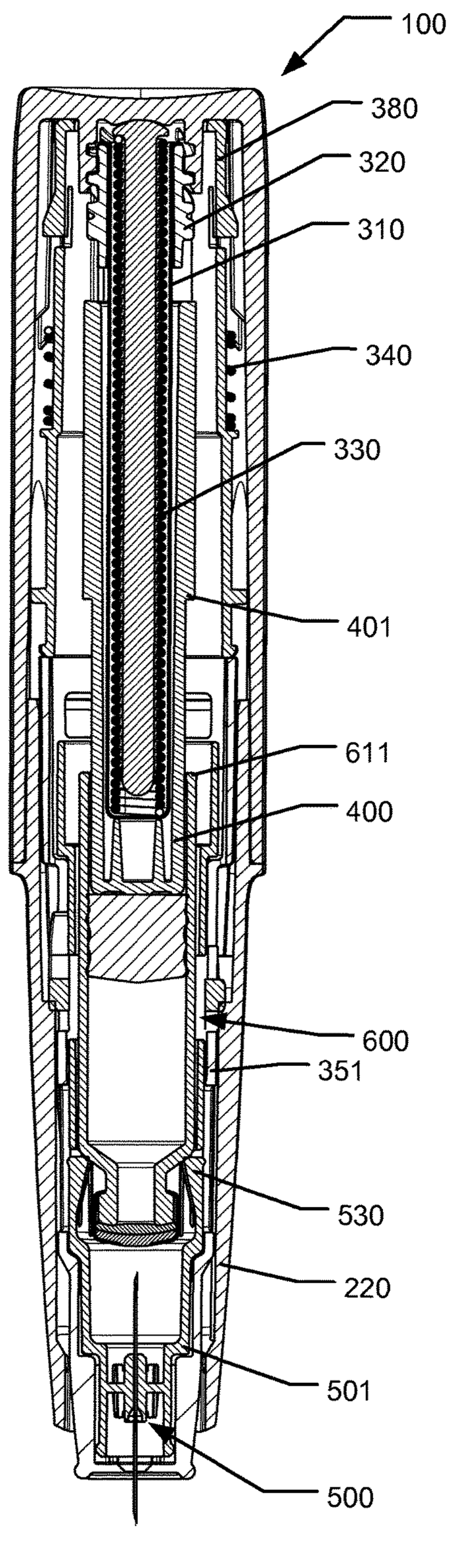

100
380
320
310
340
330
401
611
400
600
351
530
220
501
500

Fig. 2b

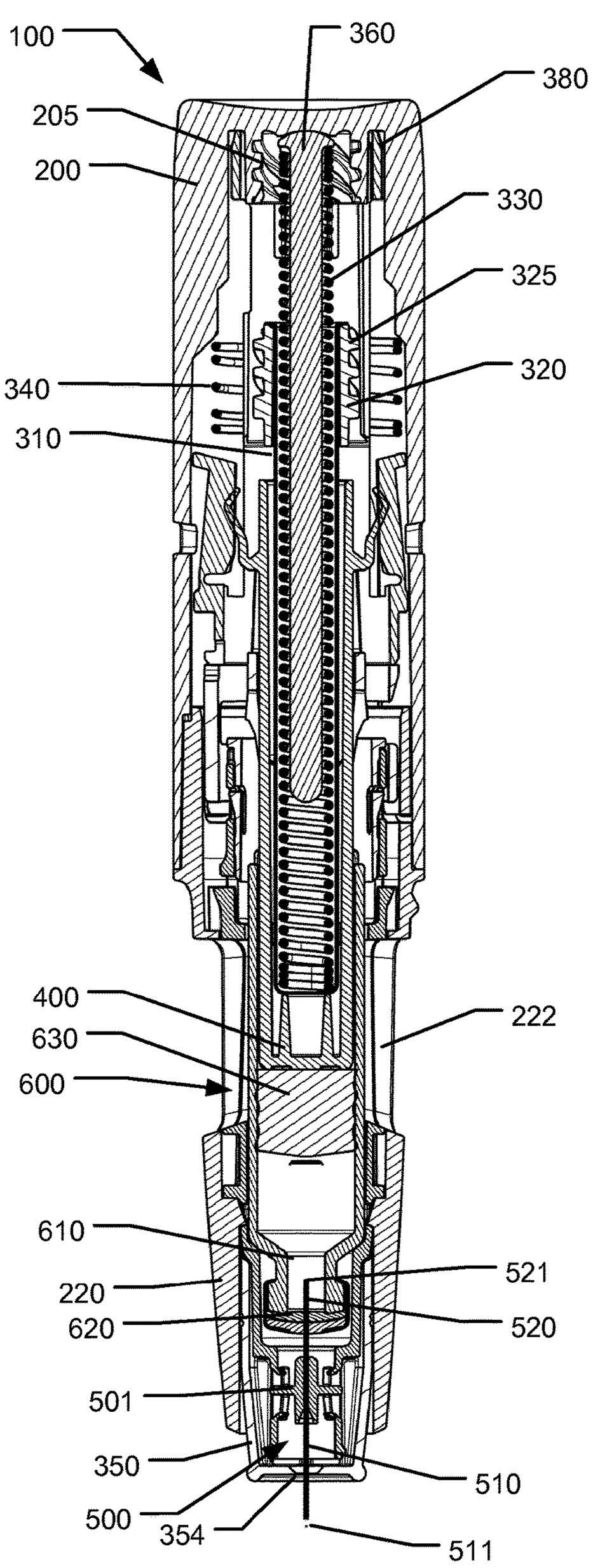

100
360
380
205
200
330
325
340
320
310
400
630
600
222
610
521
220
520
620
501
350
510
500
354
511

Fig. 3a

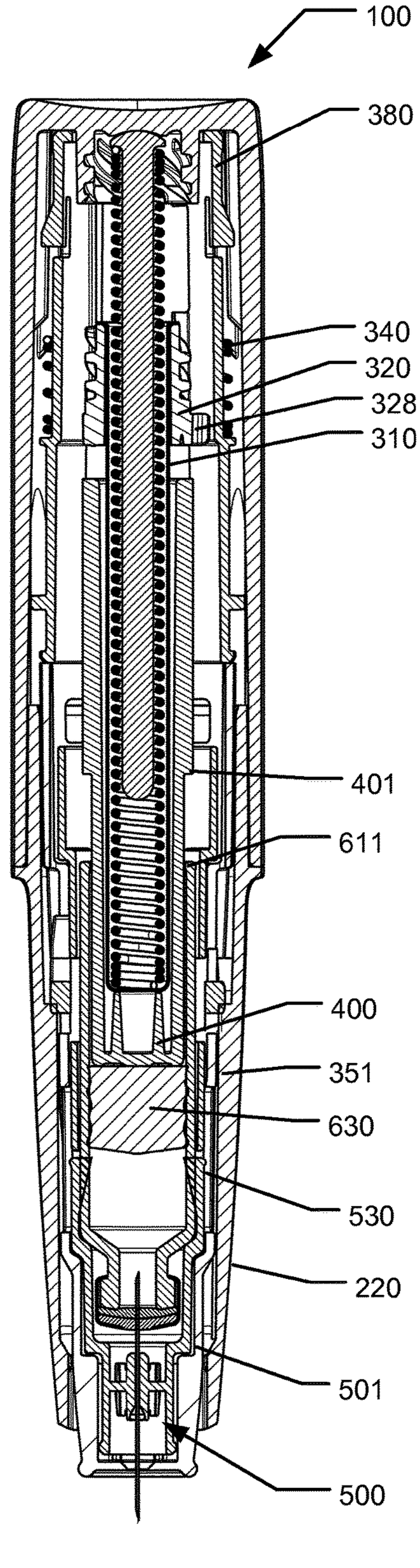

100
380
340
320
328
310
401
611
400
351
630
530
220
501
500

Fig. 3b

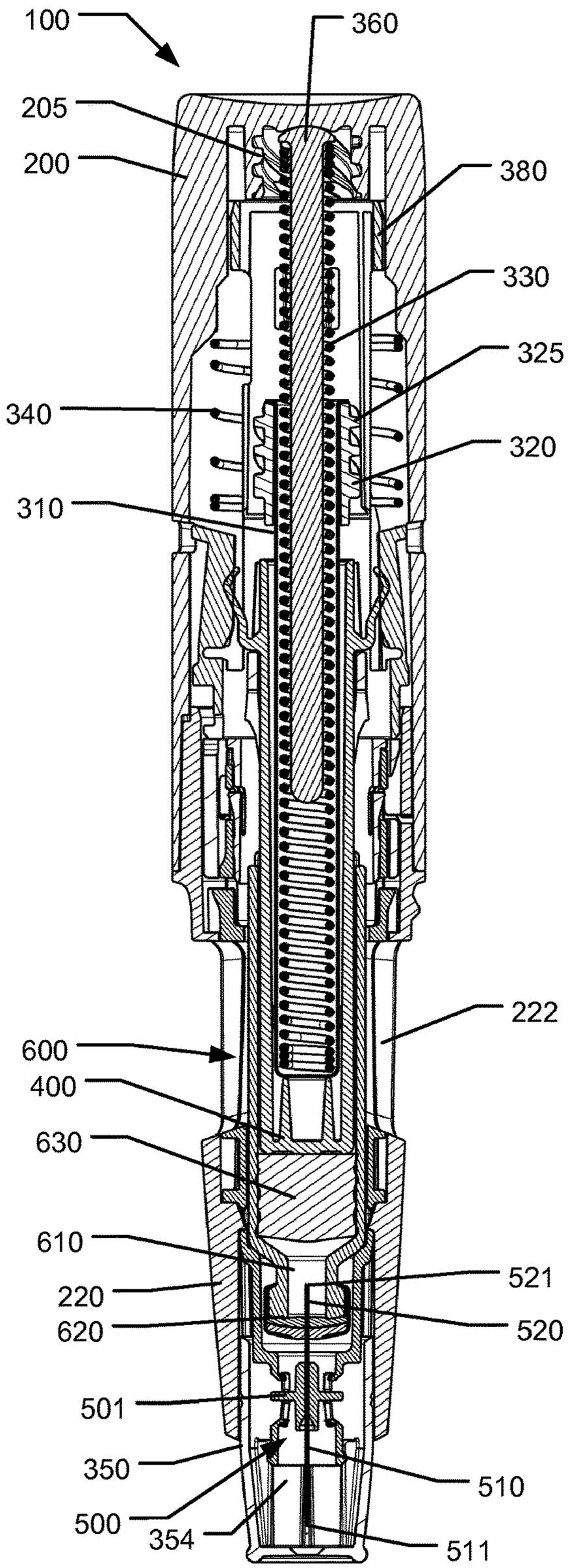

100
360
205
200
380
330
325
340
320
310
222
600
400
630
610
220
620
521
520
501
350
500
354
510
511

Fig. 4a

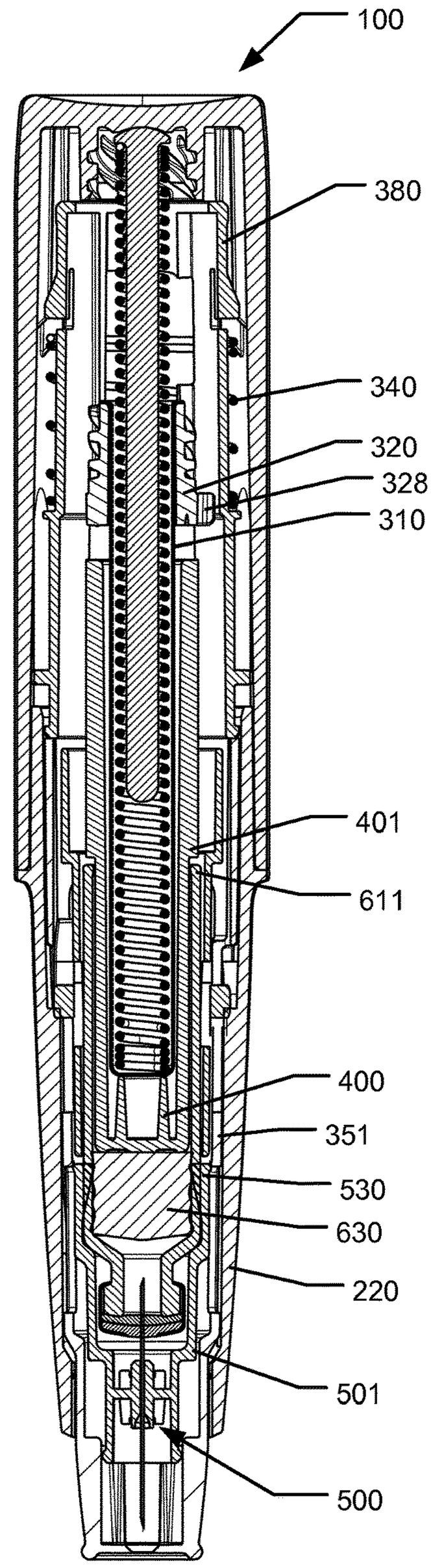

100
380
340
320
328
310
401
611
400
351
530
630
220
501
500

Fig. 4b

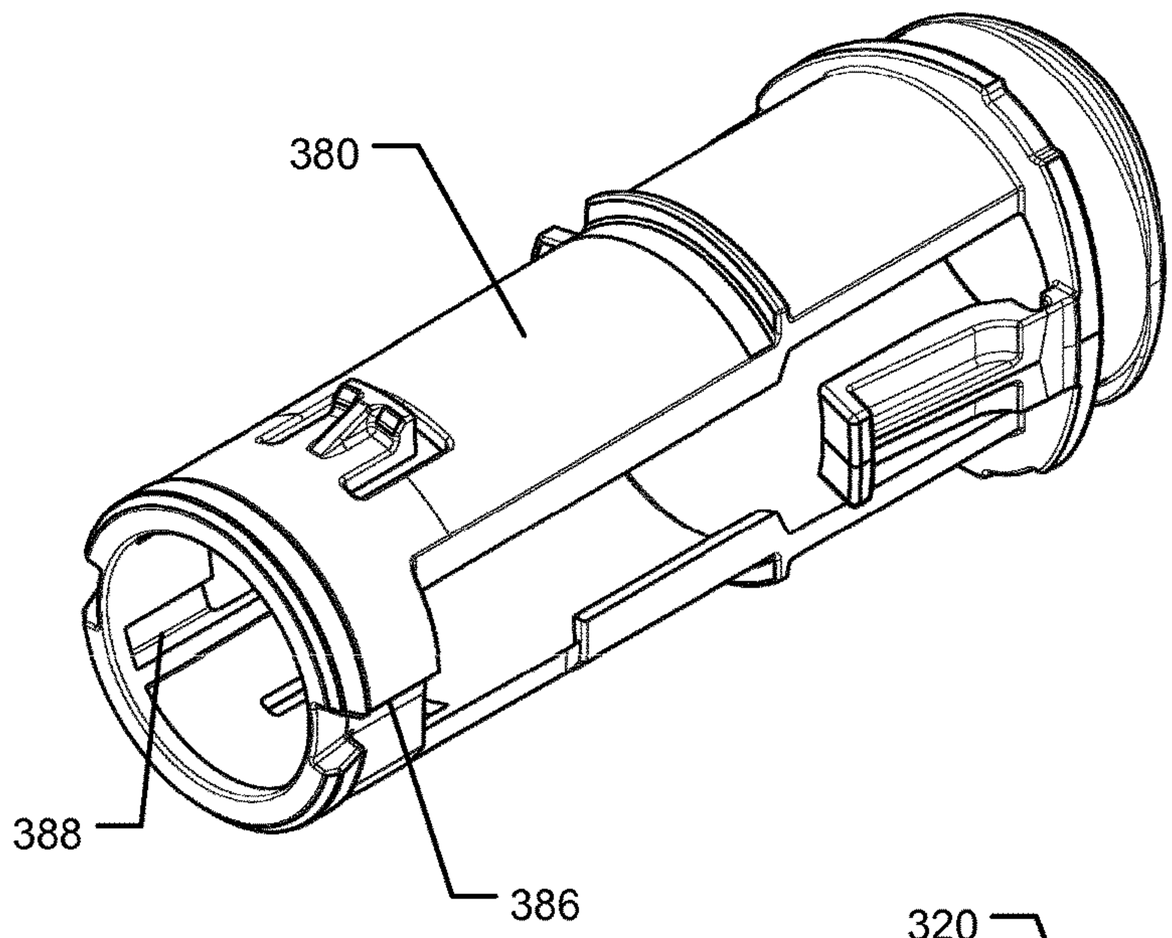


Fig. 5

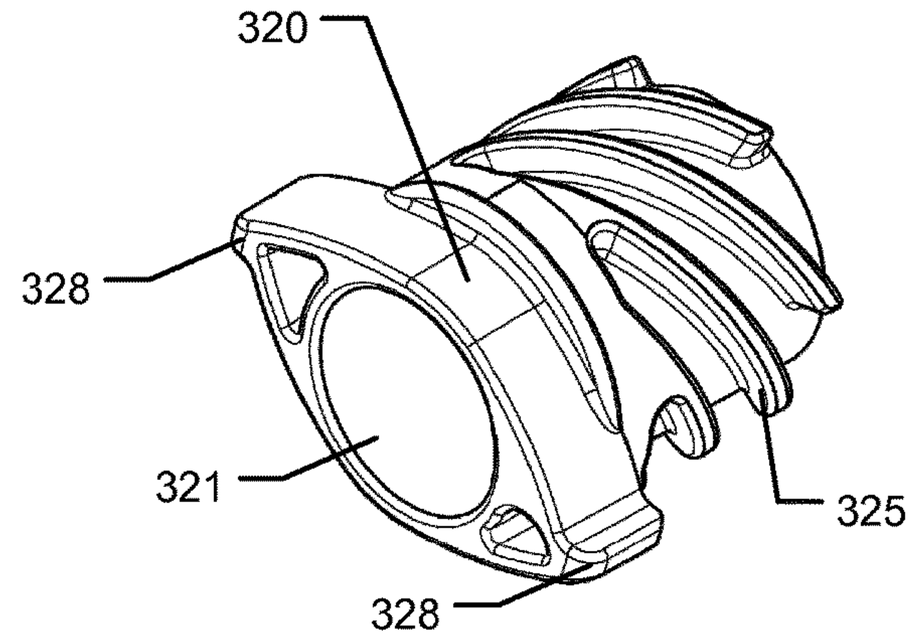


Fig. 6

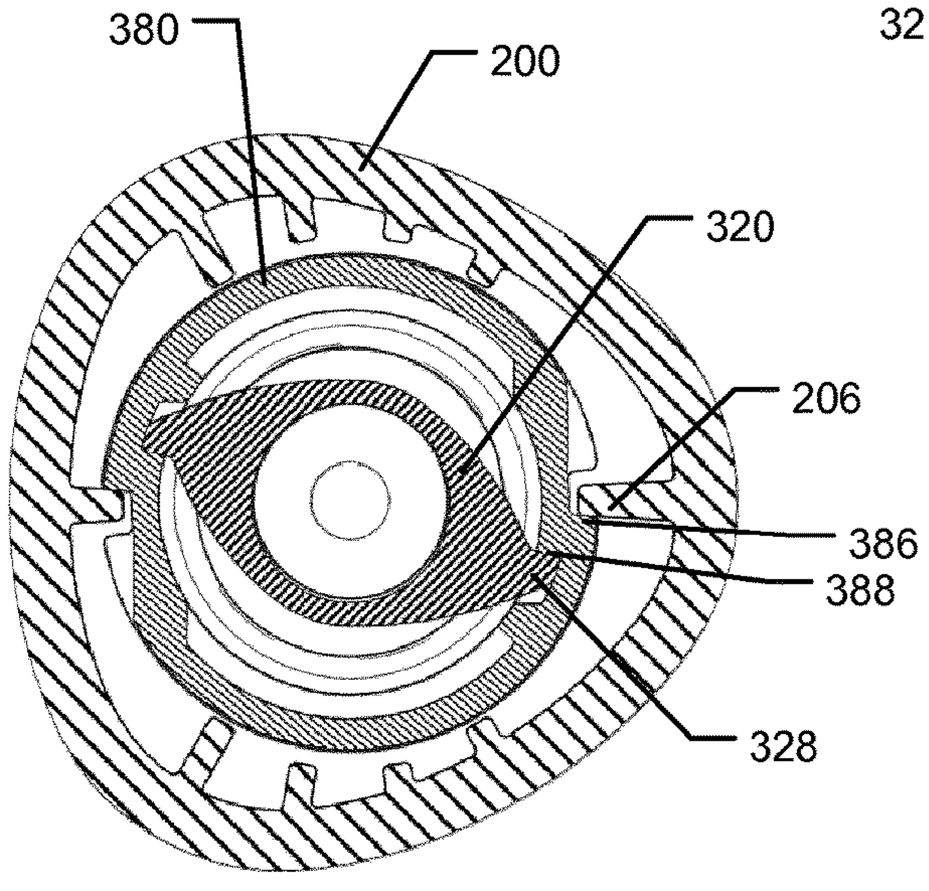


Fig. 7

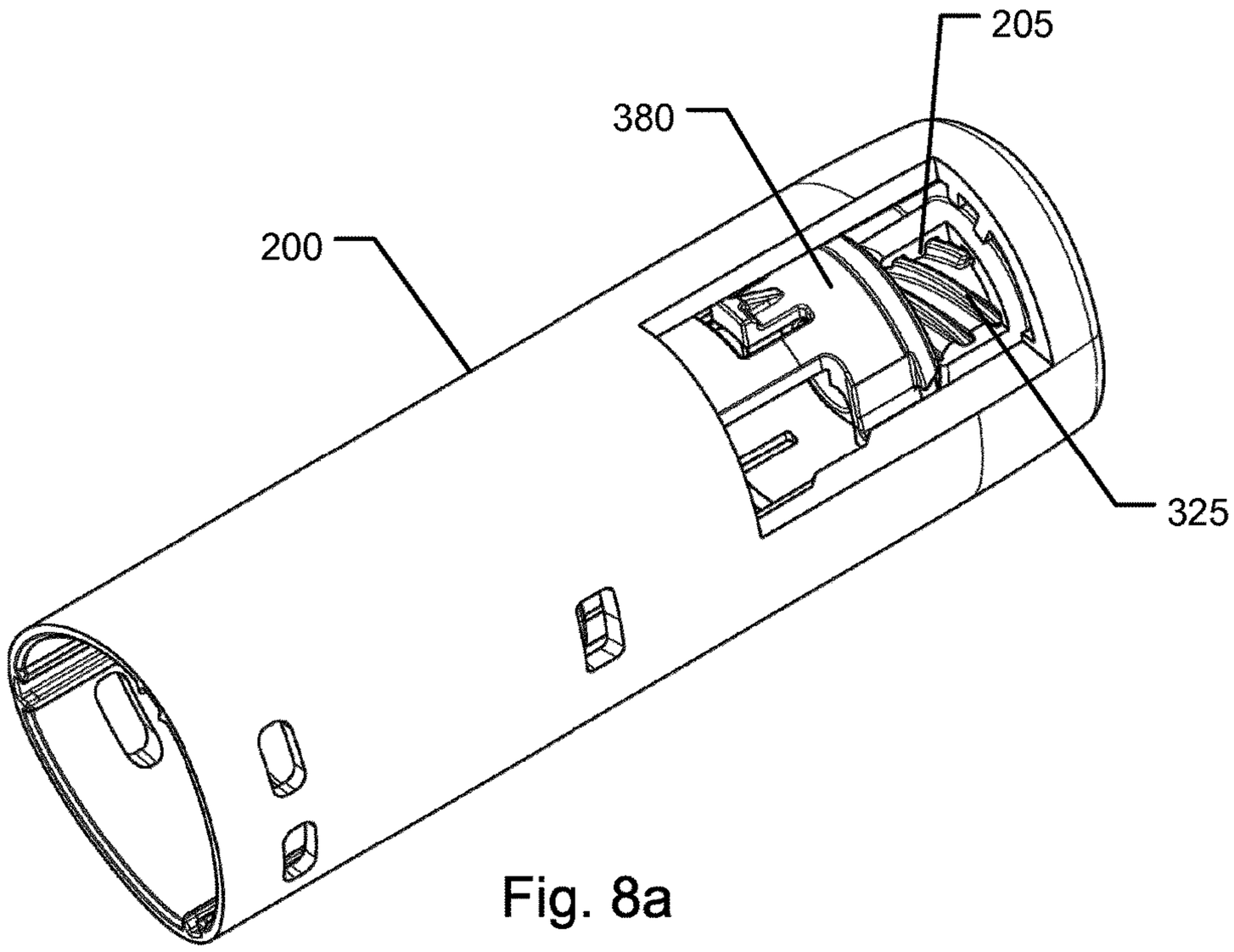


Fig. 8a

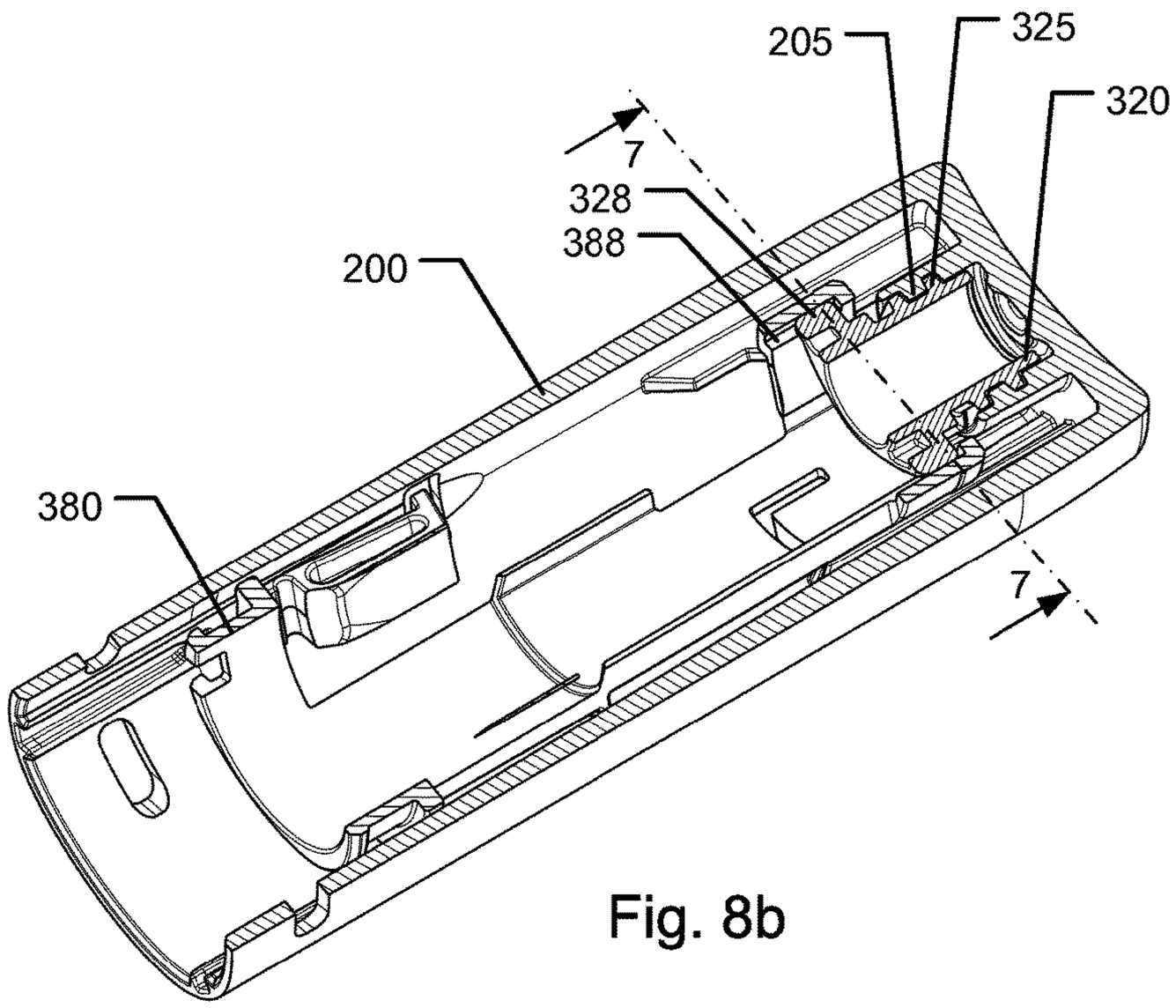


Fig. 8b

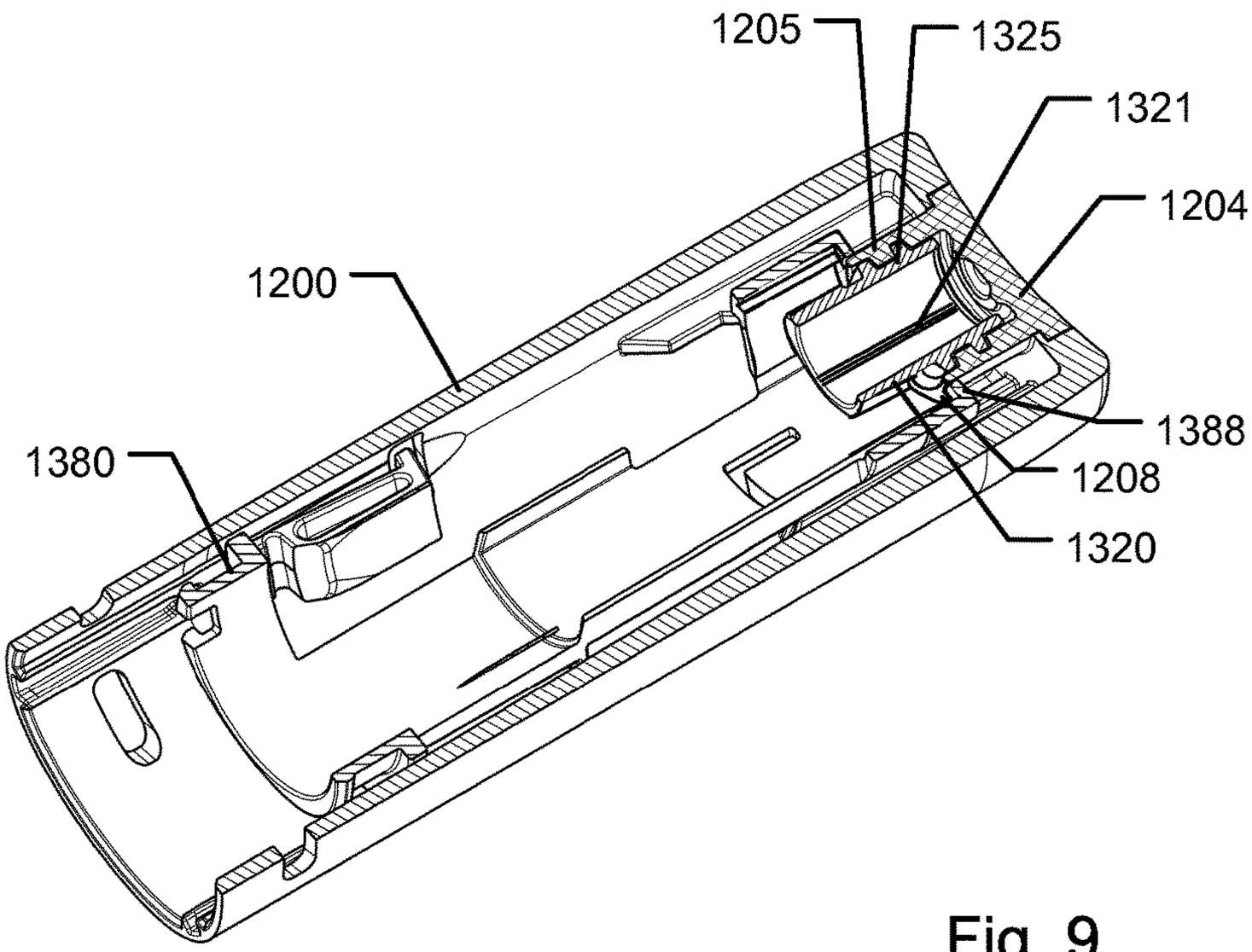


Fig. 9

AUTOINJECTOR HAVING NEEDLE SHIELD TRIGGERING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 35 U.S.C. § 371 National Stage application of International Application PCT/EP2015/057526 (published as WO2015/150578), filed Apr. 7, 2015, which claims priority to European Patent Application 14163586.2, filed Apr. 4, 2014; the contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to injection devices for injecting a medicament. In particular the present invention relates to autoinjector devices for injecting a medicament from a held cartridge and improvements relating to the performance of such injection devices.

BACKGROUND OF THE INVENTION

In relation to some diseases patients must inject a medicament on a regular basis such as once weekly, once daily or even a plurality of times each day. In order to help patients overcome fear of needles, fully automatic injection devices have been developed with the aim oft making the use of the injection device as simple as possible. Such devices are typically designed such that a user shall position the injection device onto the injection site and activate the device. Such activation causes the device to insert a needle into the skin, eject a dose of the medicament and subsequently move the needle into a shielded position.

Generally, for injection devices of the above type, main attention has been directed towards devices equipped with a glass cartridge where a needle cannula is fixedly attached to the outlet end of a cartridge. Such needle cannula is initially being covered in a sterile way by a cap member that during storage acts as a stopper for the needle cannula, and which requires removal prior to use. Typically, these devices further include a needle shield portion for shielding the needle before and/or after use. Disclosure of such devices is included in U.S. Pat. Nos. 7,449,012, 7,717,877 and WO2008/116688.

Some manufacturers prefer the type of cartridge having a pierceable septum which during storage provides a seal for the cartridge outlet and where the septum, upon use, is pierced by a needle cannula. Prior art devices using this type of cartridge are disclosed in U.S. Pat. Nos. 2,752,918, 5,658,259, 6,743,203, 6,210,369 and WO94/07553. Devices of that type hold a needle assembly and a cartridge in a separated storage configuration which upon activation of the device allows for subsequent connection to establish fluid communication between cartridge and needle assembly. In addition, automatic penetration of the needle into the skin of the user for subsequent automatic delivery of the medicament is typically incorporated.

While the above devices aim at providing a high level of automation, injection devices that provide automatic insertion of the needle into the dermis also prevent the user from controlling the insertion, which can lead to uneasiness for the user.

Injection devices that provide automatic delivery of the medicament, i.e. auto-injectors, typically use a drive spring as driving force for the injection. Before use, the drive spring will be held in a pre-tensioned position from which it is released upon activation of the device. After activation the drive spring uses the energy from the tension to drive forward the piston of a cartridge.

One problem associated with auto-injectors having needle shield operated triggering is that the release mechanism typically relies on at least one component that is exerted to excessive forces and that maintains the drivespring in a state where the plunger can be released for expelling the medicament of the cartridge. The triggering principle typically relies on at least one component that is deformed to unlock for releasing energy from the drive spring. Due to the excessive forces provided by the drive spring such principle often results in non-optimal performance of the needle shield movement.

Having regard to the above-identified prior art devices, it is an object of the present invention to provide an autoinjector that is improved regarding needle shield triggering by movement of a needle shield and which enables improved control of the device during operation.

Yet additional further objects of the invention are to provide measures for obtaining devices having a superior performance and, at the same time, enabling manufacture at a reduced cost.

BRIEF DESCRIPTION OF THE INVENTION

In a first aspect, the present invention relates to an autoinjector for expelling a single dose of drug from a held cartridge, comprising:

a base,

a drug cartridge arranged relative to the base, the cartridge comprising:

a) an elongated body having a distal end and a proximal end and defining a central longitudinal axis, the body having a distally arranged outlet adapted for connection to a needle, and

b) a piston accommodated in the body, the piston configured for being driven axially in the distal direction to expel a dose of a drug through the outlet,

a plunger adapted for cooperation with the piston,

an actuating spring arranged to act on the plunger to drive the piston distally,

a needle shield axially movable relative to the base between an extended position and a collapsed position,

wherein the autoinjector defines a lock configured for releasably maintaining the plunger in an initial axial position where the actuating spring is tensioned, the lock being operated by the needle shield,

wherein the plunger defines a plunger thread and the base defines a base thread adapted to cooperate with the plunger thread,

wherein prior to activation, a) the plunger thread engages the base thread and b) the lock acts to prevent relative rotation between the plunger and the base, thereby maintaining the plunger in the initial axial position, and

wherein, upon the needle shield being moved towards the collapsed position, the lock is released to enable relative rotation between the plunger and the base causing release of the plunger from the initial axial position and expelling the dose of the drug.

In the autoinjector according to the first aspect, the device includes a needle shield triggered expelling assembly where a pre-stressed actuating spring is actuated for releasing axial movement of the plunger by a movement of the needle shield relative to the base. As the energy accumulated in the actuating spring is not changed when the needle shield is moved axially from the extended position to the collapsed

position, the force exerted on the needle shield for performing this movement is not counteracted by the force exerted by the actuating spring.

In some embodiments, the base forms a housing of the device. In some embodiments, the autoinjector accommodates a needle that is fixedly mounted relative to the base. The needle comprises a front needle and may comprise a rear needle.

In some embodiments, the front needle is configured to be manually operable relative to the needle shield such that when the needle shield is held against an injection site, manual operation of the front needle relative to the needle shield or vice versa causes manual penetration of the front needle into the injection site and causes subsequent release of the lock. When the lock is released the autoinjector becomes triggered.

According to the first aspect of the invention, by configuring the device so that a pushing force exerted manually on a part of the device is transferred to a manual force acting on the needle for manual penetration of the front needle into the injection site, the user gains improved control of the insertion of the injection needle. At the same time, by using this configuration the needle is hidden from the user during an administration. By providing an improved control of the needle insertion procedure a potential uneasiness for the user can be alleviated. The first part of the activation movement moves the needle forward relative to the needle shield to insert the needle in the user's skin. The second part of the movement activates the expelling assembly. This allows the user to manually insert the needle before activating the device and an administration may be stopped in time should the user wish to abort the operation.

The needle may incorporate a sterility barrier either for the front needle, for the rear needle or for both. In some embodiments, the each of the sterility barriers may be formed as a flexible sheath configured as a closed cavity for accommodating at least a part of the respective ones of the front needle and the rear needle. The needle may from part of a needle assembly including a needle cannula having a front needle and a rear needle respectively protruding in the distal and proximal directions from a needle hub. The needle assembly may include front and rear covers forming sterility sheaths for the front needle and rear needle respectively. Each of the front and the rear covers may be formed as a rubber sheath which is penetrable by the pointed tip of the needle when the cover is forced towards the needle hub.

The injection device may comprise an actuator in the form of a stored energy source coupled to a drive ram and configured for driving the drive ram upon release of the lock. The energy source may be provided as a stored energy source, such as an actuating spring or a pre-strained spring, a compressed gas etc. In other forms, the energy source is configured to become charged during an initial operation of the device prior to activation of the injection mechanism.

In particular forms, the actuator is provided as a helical compression spring that exerts an axial force on the plunger. The plunger may include a drive ram and a spacing member positioned between the drive ram and the piston of the held cartridge.

In some embodiments the autoinjector may include a needle shield spring which is associated with the needle shield and the needle to urge the front needle into its shielded state or to urge the needle shield into the state where the front needle is shielded. In some embodiments the needle shield spring is an element separate from the actuator or the actuating spring.

In some embodiments of the autoinjector, the lock includes a first lock element that is axially movable as the needle shield moves from the extended position towards the collapsed position. The first lock element and the plunger define respective cooperating lock geometries configured to, prior to activation, maintain a rotational lock between the plunger and the base, the cooperating lock geometries being adapted to unlock to enable rotation between the plunger and base upon the needle shield being moved towards the collapsed position.

In some embodiments of the autoinjector, the first lock element is prevented from rotating relative to the base and wherein the lock element and the plunger define respective cooperating lock geometries configured to, prior to activation, maintain a rotational lock between the plunger and the lock element, the cooperating lock geometries being adapted to unlock to enable rotation between the plunger and the lock element upon the needle shield being moved towards the collapsed position.

In some embodiments of the autoinjector the base thread is fixedly associated with the base.

In some embodiments the lock element defines a first lock feature and the plunger defines a cooperating lock feature, wherein one of the first lock feature and the cooperating lock feature defines an axial track and wherein the other of the first lock feature and the cooperating lock feature defines a track follower. In such embodiment the axial track may be formed as a track that extends in a direction parallel with the central longitudinal axis.

Hence, when the needle shield is moved from the extended position towards the collapsed position, the lock is released without inducing a relative rotation between the lock element and the plunger.

In some embodiments of the autoinjector the base thread is defined by a rotatable component that is axially fixed but rotatable mounted relative to the base, wherein the plunger thread is prevented from rotating relative to the base, wherein the lock includes a first lock element that is axially movable as the needle shield moves from the extended position towards the collapsed position, wherein the lock element and the rotatable component define respective cooperating lock geometries configured to, prior to activation, maintain a rotational lock between the rotatable component and the base, the cooperating lock geometries being adapted to unlock to enable rotation between the rotatable component and the base upon the needle shield being moved towards the collapsed position.

In some embodiments of the autoinjector the first lock element is prevented from rotating relative to the base and wherein the lock element and the rotatable component define respective cooperating lock geometries configured to, prior to activation, maintain a rotational lock between the rotatable component and the lock element, the cooperating lock geometries being adapted to unlock to enable rotation between the rotatable component and the lock element upon the needle shield being moved towards the collapsed position.

In some embodiments of the autoinjector the plunger thread is rotationally fixed relative to the plunger and the plunger is rotationally fixed relative to the base.

In some embodiments of the autoinjector the plunger thread is engaged with the base thread during an initial first axial displacement of the plunger and where the plunger thread is released from engagement with the base thread allowing the plunger to subsequently continue axial displacement in a second axial displacement.

In some embodiments of the autoinjector an external diameter of the plunger thread is larger than the internal diameter of a cylindrical section of the cartridge.

In some embodiments of the autoinjector the plunger thread is accommodated at the proximal end of the plunger.

In some embodiments of the autoinjector the actuating spring is a helical compression spring arranged internally in a longitudinal bore of the plunger.

In some embodiments of the autoinjector the device irreplaceably accommodates a cartridge within the base and wherein the cartridge cannot be removed from the device without the use of tools.

In some embodiments of the autoinjector the force acting for causing rotation between the plunger and the base for releasing the plunger from the initial axial position is at least partly exerted by the actuating spring.

In some embodiments, the force acting for causing rotation between the plunger and the base for releasing the plunger from the initial axial position is exclusively exerted by the actuating spring.

In some embodiments, an externally applied force on the needle shield for causing the needle shield to be moved into the collapsed position is not transmitted into a force component acting to cause rotation between the plunger and the base for releasing the plunger from the initial axial position.

The cartridge body may define a proximally facing rear surface. The distally arranged outlet of the cartridge may comprise a pierceable septum adapted to be pierced by the rear needle of a needle assembly having both a front needle extending in the distal direction and a rear needle extending in the proximal direction. In alternative configurations, the cartridge body outlet portion includes an injection needle fixedly attached relative to the cartridge body.

In some embodiments, the actuator may be capable, upon release of the lock, to cause the cartridge and the rear needle to enter into the state where the cartridge septum is pierced by the rear needle and subsequently to cause the drive ram to move to dispense the medicament through the needle.

The injection device may incorporate an activator which is mechanically associated with the needle so that when the activator and the needle shield is moved relative to each other it causes the front needle and the needle shield to move relative to each other. In some embodiments the needle substantially follows movement of the activator as the activator moves relative to the needle shield.

In some embodiments the activator is configured to define a housing section which at least partly accommodates the cartridge and where the housing section is adapted to be gripped by the hand of the user. In such embodiment, the activator may be coupled to the needle to transfer a force from the activator to the needle when the activator is moved relative to the needle shield.

As used herein, the term "medicament" is meant to encompass any medicament-containing flowable drug capable of being passed through a delivery means such as a hollow needle or cannula in a controlled manner, such as a liquid, solution, gel or fine suspension. Also lyophilized drugs which prior to administration are dissolved into a liquid form is encompassed by the above definition. Representative medicaments includes pharmaceuticals such as peptides, proteins (e.g. insulin, insulin analogues and C-peptide), and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form.

DETAILED DESCRIPTION OF THE INVENTION

The invention will now be described in further detail with reference to the drawings in which:

FIGS. **1***a* and **1***b* shows sectional front and side views of an exemplary embodiment of a first type injection device **100** according to the invention, the injection device being in an initial shielded state,

FIGS. **2***a* and **2***b* shows sectional front and side views of the device **100** illustrating a state where a front needle fully protrudes from a needle shield,

FIGS. **3***a* and **3***b* shows sectional front and side views of the device **100** illustrating a state where the cartridge has been connected to the needle for fluid delivery and wherein expelling has been initiated,

FIGS. **4***a* and **4***b* shows sectional front and side views of the device **100** illustrating a state where a predetermined dose of medicament from the cartridge has been expelled and the needle shield has returned to the shielded state,

FIG. **5** is a detailed perspective view of a trigger element of the device **100**,

FIG. **6** is a detailed perspective sectional view of a release nut of the device **100**,

FIG. **7** shows a cross sectional view of a release nut assembly of the injection device **100**,

FIG. **8***a* is a partly cut perspective view of a top housing section of the injection device **100**,

FIG. **8***b* is a cross sectional perspective view of the release nut assembly of the injection device **100**, and

FIG. **9** shows a schematic representation of the main components for an alternative trigger release mechanism of an autoinjector of a second type.

The following is a description of an exemplary embodiment of a medical injection device **100** for administering a pre-determined amount of a liquid medicament. FIGS. **1***a* through **4***b* show various states of the injection device **100** during operation thereof with different views offering a detailed assessment of the operating principles.

Injection device **100** includes a generally tubular housing that extends along a central longitudinal axis. The housing forms a base that includes a lower housing section **220** arranged at a distal end of the device and a top housing section **200** arranged at a proximal end of the device. The lower housing section **220** and the top housing section **200** are joined to each other to form an enclosure to accommodate a medicament cartridge **600**.

Injection device **100** may further include a removable protective cap (not shown) that attaches to a distal end of the device **100** to protect a needle end of the device **100**. The lower housing section **220** includes two opposing windows **222**. When the cap has been removed from the device **100**, the windows **222** allow visual inspection of the medicament contained within the device **100**. In addition, windows **222** allow a user of the device to determine whether or not the device **100** has been used for an injection by inspecting the presence or the location of a piston of a medicament cartridge **600** arranged within the housing. In the shown embodiment top housing section **200** is for manufacturing reasons formed as an element separate from but permanently fixed to lower housing section **220** but may in alternative embodiments be formed integral with lower housing section **220**.

FIGS. **1***a* and **1***b* show front and side sectional views of the device **100** after the protective cap has been removed but in a condition prior to the administration operation. Shown protruding from the distal end of the lower housing section **220** is a needle shield **350** which is arranged coaxially and slidable relative to lower housing section **220**. Needle shield **350** is slidable relative to the housing between a distal extended position where a front end of a needle assembly **500** arranged internally in lower housing section **220** is in a

shielded state and a second proximal collapsed position where a front needle end of the needle assembly **500** protrudes through an aperture **354** arranged in the central part of a distal wall surface of the needle shield **350**.

The injection device **100** is configured for being triggered to inject a dose when the needle shield **350** is moved from the distal extended position towards the collapsed position. The protective cap, when attached to the lower housing section **220**, prevents the needle shield **350** from being manipulated and thereby prevents premature triggering of the injection device **100**.

Lower housing section **220** accommodates a medicament filled cartridge **600** having an outlet **610** covered by a cartridge septum **620** adapted to be pierced by a needle for establishing fluid communication with the cartridge interior and having a slidably arranged piston **630**. Piston **630** is driveable towards the outlet **610** when a needle pierces the cartridge septum **620** in order to dispense medicament from the cartridge **600**. The dispensing is controlled by an expelling assembly. Cartridge **600** is arranged movable with respect to the lower housing section **220** from a proximal storage position to a distal active position.

Distally in the lower housing section **220** is a needle unit in the form of a needle assembly **500** arranged in an initially separated configuration with respect to cartridge **600**. In the shown embodiment, needle assembly **500** includes a needle cannula having a front needle **510** and a rear needle **520** respectively protruding in the distal and proximal directions from a needle hub **501**. Both front needle **510** and rear needle **520** include pointed tips **511** and **521** for respectively piercing the skin of a user and the cartridge septum **620**.

Although not shown in the figures, the needle assembly **500** furthermore may include front and rear covers forming sterility sheaths for the front needle **510** and rear needle **520** respectively. Each of the front and the rear covers may be formed as a rubber sheath which is penetrable by the pointed tip of the needle **511/521** when the cover is forced towards the needle hub **501**. Prior to use of the device, each of the two covers assumes the extended position in which the cover seals of the respective one of the front **510** and rear needle **520**. The front and rear covers may be attached to the hub **501** either by gluing, welding, interference fit, a separate mounting element, or similar.

The needle cannula may be attached to the hub **501** by gluing, interference fit or similar joining process. In the embodiment shown, the hub **501** is an element separate from the housing but may in alternative embodiments be formed as a part of the housing **200/220**. Hub **501** is formed as a generally tubular structure which extends proximally along the cartridge and even further to a position proximal to the cartridge. In this way the hub **501** supports the cartridge **600** along an exterior cylindrical wall of the cartridge. As such, the hub **501** is designed to perform as a cartridge holder relative to which the cartridge **600** is allowed to axially slide between the proximal storage position and into the distal active position.

In the shown embodiment, the needle hub **501** and hence the needle cannula is axially mounted relative to the housing of the device **100** so that the needle cannula follows axial movements of the housing when the housing is moved relative to the needle shield **350**.

In the shown embodiment, the needle shield **350** is formed as a generally tubular member having a distal face arranged to initially cover the front needle **510**. The needle shield **350** is mounted slidable relative to the lower housing section **220** allowing limited axial movement by a predefined axial distance.

The needle shield **350** cooperates with a trigger element **380** which is located proximally to the needle shield **350**. Trigger element **380** is also formed as a generally tubular element and extends axially in the proximally direction from the needle shield to a location close to the proximal end of top housing section **200**. In the assembled state of the device **100**, the needle shield **350** and the trigger element **380** perform as a single entity, i.e. the movement of trigger element **380** follows axial movement of the needle shield **350**. Hence the trigger element **380** is movable from a distal position corresponding to the extended position of the needle shield **350** to a proximal position corresponding to the collapsed position of the needle shield **350**. In the shown embodiment, each of the needle shield **350** and the trigger element **380** are mounted in a way that prevents rotational movement relative to the housing **200/220**.

The trigger element **380** is urged in the distal direction by means of shield spring **340** so that when no external applied force is exerted on the needle shield, the needle shield assumes its distal extended position which is shown in FIGS. **1***a* and **1***b*. In this position a stop geometry on trigger element **380** and/or needle shield **350** prevents the two components from moving further in the distal direction. When an externally applied force is exerted on the needle shield **350** for moving the needle shield in the proximal direction relative to the housing, such as when device **100** is pressed with the needle shield against an injection site, the externally applied force acts counter to the force provided by the needle shield spring **340** resulting in the needle shield **350** and the trigger element **380** being forced to move in the proximal direction. When the needle shield **350** assumes the proximal collapsed position a proximal end surface of the trigger element **380** prevents the trigger element and the needle shield **350** from moving further proximally relative to the housing (cf. FIGS. **2***a* and **2***b*).

As the device **100** is removed from the injection site, the needle shield **350** will move distally due to the force from the shield spring **340**. After an injection has been performed, as the needle shield **350** reaches its distal position again, as shown in FIGS. **4***a* and **4***b*, it will be locked in this position to render the needle shield inoperable (to be further explained below).

The needle assembly **500** is arranged at the distal end of the lower housing section **220**, such that the needle shield **350** completely covers the needle assembly when the needle shield is in its extended position. When the needle shield **350** is in its proximal collapsed position, the front needle **510** protrudes through the aperture **354** of needle shield **350**.

As indicated in FIG. **1***b*, the cartridge **600** is maintained in its proximal storage position by means of two resilient arms **530** that extend radially inwardly from the needle hub **501**. In the initial state shown in FIG. **1***b*, the resilient arms **530** assume a position where they support and retain a neck portion of the cartridge **600** to prevent the cartridge from moving in the distal direction. The resilient arms **530** are adapted to flex radially outwards when sufficient force acting to move the cartridge **600** in the distal active position is exerted on cartridge **600**. However, in the initial state where the needle shield **350** assumes its distal extended position, a blocking geometry **351** of the needle shield **350** encircles the resilient arms **530** to prevent them from flexing outwards and thus prevents the cartridge **600** from being moved distally. As will be described later, the blocking geometry **351** is configured to move axially when the needle shield **350** is moved into its proximal collapsed position making room for the resilient arms **530** to be flexed radially outwards.

The expelling assembly of injection device **100** is based on a plunger device that is driven in the distal direction along the central longitudinal axis of the device for advancing the piston **630** to thereby expel a dose from the cartridge **600**. The plunger device in the shown embodiment includes a drive ram **310** and a spacer member **400**. In device **100** an actuator **330** is arranged in the proximal part of the device providing a stored energy source for exerting a distally directed force on drive ram **310**. Spacer member **400** is a generally tubular member that is positioned between drive ram **310** and the piston **630** of the cartridge **600**. Spacer member **400** acts as an intermediary member for transferring a force exerted by the drive ram **310** on the piston **630** for forwarding the piston in the distal direction.

The actuator is provided in the form of actuating spring **330** that in the shown embodiment is provided as a pre-stressed helical compression spring. The actuating spring **330** is energized by straining the compression spring during manufacture of the device. The drive ram **310** is furthermore hollow to allow the actuating spring **330** to be positioned within the drive ram **310**. A guiding element **360** arranged internally in actuation spring **330** assists in guiding the actuation spring **330** to prevent it from bending sideways. Guiding element **360** provides at its proximal end a seat portion arranged to act as a seat for supporting the proximal end of actuation spring **330**.

The spacer member **400** is formed with stop surfaces **401** positioned a predetermined distance from the distal end of spacer member **400** to cooperate with the rear end **611** of the cartridge **600** to thereby define a precise end of stroke position for the piston **630** inside cartridge **600**. As the piston **630**, during filling of the cartridge **600**, can be accurately positioned with respect to the rear end **611** of the cartridge **600**, the exact volume of an expelled dose can be accurately controlled by utilizing the stop surfaces **401** hitting the rear end **611** of cartridge **600** at completion of the expelling operation.

In the embodiment shown, spacer member **400** and a cooperating member associated with the housing may further include one or more pairs of click generating elements such as protrusions adapted to cooperate with click arms to generate click sounds during and/or at the completion of the injection.

As mentioned, in the shown embodiment the actuator in the form of a pre-stressed actuation spring **330** urges the drive ram **310** in the distal direction. In the unactivated state of the injection device **100**, a release nut **320** associated with drive ram **310** cooperates with the top housing section **200** and the trigger element **380** to retain the drive ram **310** in an initial axial position against the force of the actuation spring **330**. Upon activation of the expelling assembly, i.e. by operating the trigger element, the release **320** nut is released allowing the drive ram to thrust forward for providing a distally directed force on the piston **630**.

Alternatively to using a pre-stressed spring which is compressed during manufacture of the device, the device may include a mechanism for compressing the spring as an initial procedure when putting the device into use. Also, the actuator may in other embodiments be formed as a torsion spring which is pre-stressed to exert a torsion force for driving forward a rotational drive of the expelling assembly. Alternatively, the actuator may be in the form of a compressed medium such as a gas. Still alternatively, the actuator may include a gas generator such as an electro-chemical cell.

The drive ram **310** is provided as a deep-drawn metal tube extending along the central longitudinal axis and defining a closed distal end and an open end portion having a collar extending radially outwards at its proximal end. The release nut **320** is arranged at the proximal end of the drive ram **310** to encircle the drive ram **310**. Release nut **320** has an axial bore **321** defining a circumferential collar that rests against the collar of the drive ram **310**. In this way the release nut **320** prevents the drive ram **310** from moving in the distal direction relative to the release nut **320**.

Release nut **320** defines a thread **325** that engages a thread **205** associated with the housing when the device is in the initial state prior to triggering. A releasable lock acts to prevent relative rotation between the release nut **320** and the housing, thereby maintaining the drive ram **310** in the initial axial position.

In the shown embodiment, the lock is provided by the trigger element **380** preventing relative rotation between the release nut **320** and the housing. As shown in FIGS. **5** and **7** axial tracks **386** of trigger element **380** are configured to be engaged by respective axial ribs **206** of top housing section **200** preventing the trigger element from rotation relative to the housing but enabling axial displacement. In the shown embodiment, two radially outwards extending protrusions **328** of release nut **320** are adapted to engage corresponding axial tracks **388** extending radially inwards on an inner surface of trigger element **380** (see FIGS. **5**, **6** and **7**). The axial tracks **388** each has a limited axial length defining open neighbouring areas at a location at the distal end of axial tracks **386**. When sufficient axial displacement of release nut **320** relative to the trigger element **380** occurs, rotation of release nut **320** is enabled. But in the initial state prior to triggering, as long as the trigger element **380** is situated distally relative to a triggering point of the trigger element **380** the release nut **320** is prevented from rotating. The triggering point of the trigger element **380** is located at a point in close proximity but distally to the proximal position of the trigger element **380**.

As long as the release nut **320** is prevented from rotating relative to the housing the threaded engagement between the thread **325** of the release nut **320** and the thread **205** of the housing prevents the release nut **320** from being moved axially. Hence, prior to activation of the expelling assembly, the drive ram **310** is also prevented from being moved in the distal direction as long as the trigger element **380** is located distal to the triggering point.

The lead of the threaded connection **325**/**205** and the dimensions of the engagement between the protrusions **328** and the axial tracks **388** are so configured that, upon displacement of the trigger element **380** towards the triggering point, once the release nut **320** has been released for rotation, the protrusions **328** cannot reengage the axial track **388**. Hence, once the expelling assembly has been activated by exerting a force on the needle shield **350** for triggering the device, in case of a potential release in the force exerted on the needle shield, the distal movement of the drive ram **310** cannot be interrupted, i.e. the drive ram **310** will continue its distal movement until the intended end of dose position defined by the elements **401**/**611**.

FIG. **8***a* shows a partly cut perspective view of the top housing section **200** wherein the trigger element are and the release nut **320** are visible. The release nut, the trigger element and the top housing section together forms a release nut assembly. For clarity, the depicted view only shows selected components of the injection device **100** in the initial state prior to triggering but wherein additional components such as the actuating spring **330** and the drive ram **310** are omitted. The engagement between the thread **325** of the

release nut **320** and the thread **325** of the housing is visible. FIG. **8***b* shows the release nut assembly in a sectional perspective view.

In the following, while mainly referring to FIGS. **1***a* through **4***a*, operation of the injection device **100** will be described.

As a first step in operating device **100**, the previously mentioned protective cap is removed from the device. As mentioned above, FIGS. **1***a* and **1***b* show the device in its initial storage condition but with the protective cap being removed from the housing **200**/**220**. The needle shield **350** is in its extended position whereby the front needle **510** is in a shielded state.

In accordance with the above description, the housing **200**/**220** acts as an activator relative to the needle shield **350**, in that, as the housing is gripped by the hand of the user and the distal end of device **100** is pressed against an injection site, the needle shield **350** will remain arrested relative to the skin and the housing moves distally relative to the needle shield **350** for activating the expelling assembly of the device **100**.

As the device **100** is activated the needle shield **350** is moved in a proximal direction relative to lower housing section **220** towards the needle assembly **500**. The movement brings the front needle **510** through the small aperture **354** in the needle shield **350**. As the needle cannula moves relative to the aperture **354** the above mentioned front cover (not shown) is preferably held back by the geometry around the opening, thereby allowing the front needle **510** to penetrate the front cover while front cover is being compressed between the needle shield **350** and the needle hub **501**. Alternatively the front cover could move through the aperture **354** as well. In such case the front cover would be pressed against the patient's skin, thereby being compressed between the device **100** and the injection site. The compression of the front cover can be either in a concertina-like way or be bent sideways, e.g. radially outwards. The front cover may have a specific geometry to ensure that the front cover is always compressed between needle shield **350** and needle hub **501**. The aperture **354** in the needle shield **350** could also have a specific geometry for ensuring correct compression of the front cover.

In the state shown in FIGS. **1***a* and **1***b* the trigger element **380** is in its distal position due to the pressure exerted by the shield spring **340**. The releasable lock that rotationally locks the release nut **320** relative to the housing is enabled and the drive ram **310** is therefore in its initial position. The cartridge **600** is positioned in its proximal storage position.

As the needle shield **350** reaches a predetermined position, i.e. the collapsed position, the needle shield **350** will reach a stop limit, see FIGS. **2***a* and **2***b*. In this state the front needle **510** will be inserted in the patient's skin and the front cover (not shown) will be compressed. In accordance with the movement of the needle shield **350**, the trigger element **380** has been moved into its proximal position, i.e. past the triggering point.

Cf. to FIG. **8***b*, as the trigger element **380** has been moved into its proximal position, the axial tracks **388** of trigger element **380** will become displaced so as to disengage from the engagement with the protrusions **328** of release nut **320**. This situation is best viewed in FIG. **2***a*. Due to the actuating spring **330** is exerting a force in the distal direction on drive ram **310** and release nut **320** the threaded engagement **325**/**205** will induce the release nut **320** to rotate. In FIGS. **2***a* and **2***b*, the release nut **320** has been rotated slightly relative to top housing section **200** and, in accordance with the threaded engagement, the release nut **320** and the drive ram **310** have been moved slightly axial towards the distal direction. The initial spacing between the drive ram **310** and the spacing member **400** has been eliminated so that the force of the actuating spring is enabled to act on the piston **630** of cartridge **600** by means of the drive ram **310** and the spacing member **400**.

The needle shield **350** and thus the blocking geometry **351** have been moved in the proximal position so that the resilient arms **530** are free to become deflected outwards. As shown in FIGS. **3***a* and **3***b* the force from the actuation spring **330** firstly displaces the drive ram **310** and the spacing member **400** and the piston **630** a distance in the distal direction. During the first part of this stage the rear needle **520** is still separated from the septum **620** of the cartridge and the cartridge is thus forced to move with the piston **630**. The force of actuating spring **330** is sufficient to overcome the force needed for deflecting the resilient arms **530** outwards. Note however, that in FIGS. **3***b* and **4***b*, the resilient arms **530** are shown superposed relative to the wall sections of the cartridge **600**. A more correct depiction of how the resilient arms **530** are actually deflected would depict the resilient arms having been deflected outwards to lie against the outer cylindrical surface of the cartridge **600**.

Initially, as the cartridge **600** moves distally, the distance between the stop surface **401** of the spacer element **400** and the rear end **611** of the cartridge **600** remains unchanged as the piston **630** generally does not move relative to the body of the cartridge **600**. However, after the cartridge **600** has been moved fully in the distal direction, the piston **630** begins its movement inside cartridge **600**, the said distance decreases.

At some point the cartridge **600** is moved fully into its distal active position where it meets a stop feature formed in the needle hub **501**. The rear needle **620** has penetrated the septum **620** of the cartridge and fluid communication between the needle cannula and the medicament contained in the cartridge **600** has been enabled. In this position the needle cannula is in contact with both the patient's skin and the medicament contained in the cartridge **600**. After fluid communication between needle cannula and cartridge **600** is established the medicament is injected into the patient by means of the drive ram **310** being now forced relative to top housing section **200** and being urged distally by actuating spring **330**. In the state shown in FIGS. **3***a* and **3***b*, the force exerted by the actuating spring **330** has acted on the drive ram **310** for expelling a first portion of the fluid from the cartridge **600**.

The actuating spring **330** continues to act on the piston **630** advancing the piston to a predefined end of dose position determined by the end of dose feature. When the stop surface **401** of spacer element **400** reaches the rear end **611** of the cartridge **600** the movement of the drive ram **310** is stopped, thereby stopping the expelling of the medicament (cf. FIG. **4***b*).

FIGS. **4***a* and **4***b* shows the injection the device **100** after it has been retracted relative to the injection site. As the device is removed the needle shield **350** is moved forward relative to the lower housing section **220**, the needle shield being urged by means of the shield spring **340**, thereby releasing the compressive pressure on the front cover (not shown). As the needle shield **350** no longer holds the front cover in a collapsed position the front cover will tend to return to its extended position covering the front needle **510**. In alternative embodiments, the front cover could remain in its collapsed position.

As the device **100** is removed from the patient the front needle **510** is removed from the skin of the patient. In

embodiments where said front cover returns to its extended position, the front cover will prevent excess medicament that is expelled from the needle cannula from dripping out of the device. The rear cover (also not shown) remains in its collapsed position due to the pressure from the cartridge **600**.

The needle shield **350** may include a lock which renders the needle shield **350** locked against proximal movements once it has been returned from the proximal collapsed position to the distal extended position, i.e. where the front needle **510** is in its shielded state.

In accordance with a first type of autoinjector described above, a trigger principle has been described wherein a plunger includes a plunger thread that is in engagement with a base thread. The plunger is maintained in pre-triggering state by means of the threaded connection wherein relative rotation is prevented. Upon being triggered, the plunger thread and the base thread are allowed to rotate relative to each other ultimately allowing the plunger to move in a distal direction.

In accordance with the general principle, in a second type of autoinjector, the above described trigger principle may be used in an alternative autoinjector which is slightly modified relative to the first type autoinjector. The modifications mainly rely in that the release nut of the plunger may be prevented from being rotated both during storage and during operation of the autoinjector. Instead the base thread may be arranged on a rotatable component which during storage is prevented from rotating relative to the housing. The rotatable component of the injector is rotatably mounted relative to the housing but may be prevented from moving axially relative to the housing. Subsequent to triggering, the rotatable component is allowed to rotate relative to the release nut in accordance with the threaded connection between the base thread component and the plunger thread component.

Reference is made to FIG. **9**, which shows the basic components needed for such a second type autoinjector. Comparing FIG. **8***b* and FIG. **9**, the above described embodiments are modified in defining a rotatable component **1204** which is rotatably mounted relative to the housing **1200** but prevented from moving axially. The rotatable component **1204** defines a base thread component **1205**. The release nut **1320** defines a plunger thread component **1325** adapted to initially engage the base thread component **1205**. The release nut **1320** is prevented from rotating relative to the housing. The means for preventing said rotation may for example be provided by forming an axial track **1321** of the release nut **1320** that engages a not shown geometry of the drive ram. The drive ram may be made non-rotatable by forming appropriate rotational locks between the drive ram, the spacing member and the housing.

In the embodiment shown in FIG. **9**, the trigger element **1380** is prevented from rotating relative to the housing **1200**. The trigger element and the rotatable component define respective cooperating lock geometries **1388**, **1208** configured to, prior to triggering, maintain a rotational lock between the rotatable component and the housing. The rotatable component **1204** is biased in an expelling rotational direction by being urged by the actuating spring. When the trigger element **1380** assumes its initial extended position, the cooperating lock geometries **1388**, **1208** engage to thereby prevent the rotatable component **1204** from rotating in the expelling rotational direction. When the autoinjector is to be triggered, the trigger element **1380** is pushed proximally towards its triggering position. This displaces the cooperating lock geometries **1388**, **1208** relative to each other. Due to threaded engagement between threads **1325**/**1205**, the force emanating from the actuating spring will tend to rotate the rotatable component **1204**. Once the trigger element **1380** has been moved proximally relative to the triggering position, rotation of the rotatable component **1204** is now allowed due to the cooperating lock geometries **1388**, **1208** become disengaged.

Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims.

The invention claimed is:

1. An autoinjector for expelling a single dose of drug from a drug cartridge, the autoinjector comprising:

a base forming a housing,

a needle that is fixedly mounted relative to the base and comprising a front needle;

the drug cartridge arranged relative to the base, the drug cartridge comprising:

an elongated body having a distal end and a proximal end and defining a central longitudinal axis, the body having a distally arranged outlet adapted for connection to the needle, and

a piston accommodated in the body, the piston configured for being driven axially in a distal direction to expel the dose of the drug through the outlet,

a plunger adapted for cooperation with the piston,

an actuating spring provided as a helical compression spring arranged to act on the plunger by exerting an axial force on the plunger to drive the piston distally,

a needle shield axially movable relative to the base between an extended position and a collapsed position,

wherein the autoinjector defines a lock configured for releasably maintaining the plunger in an initial axial position where the actuating spring is strained, the lock being operated by the needle shield, wherein manual operation of the needle shield by movement of the needle shield relative to the front needle towards the collapsed position causes manual penetration of the front needle into an injection site and causes subsequent release of the lock,

wherein the plunger defines a plunger thread and the base defines a base thread fixedly associated with the base, wherein the base thread is adapted to cooperate with the plunger thread,

wherein prior to activation, the plunger thread engages the base thread and the lock acts to prevent relative rotation between the plunger and the base, thereby maintaining the plunger in an initial axial position,

wherein, upon the needle shield being moved towards the collapsed position, the lock is released to enable the force exerted by the actuating spring to cause relative rotation between the plunger and the base causing release of the plunger from the initial axial position and expelling the dose of the drug, and

wherein the plunger thread is engaged with the housing by engaging the base thread during an initial first axial displacement of the plunger and where the plunger thread is released from engagement with the housing by releasing engagement with the base thread allowing the plunger to subsequently continue axial displacement in a second axial displacement.

2. The autoinjector as defined in claim **1**, wherein a needle shield spring biases the needle shield towards the extended position.

3. The autoinjector as defined in claim **2**, wherein the needle shield spring is an element separate from the actuating spring.

4. The autoinjector as defined in claim **1**, wherein the lock includes a first lock element that is axially movable as the needle shield moves from the extended position towards the collapsed position, wherein the first lock element and the plunger define respective cooperating lock geometries configured to, prior to activation, maintain a rotational lock

between the plunger and the base, the cooperating lock geometries being adapted to unlock to enable rotation between the plunger and the base upon the needle shield being moved towards the collapsed position.

5. The autoinjector as defined as in claim **4**, wherein the first lock element is prevented from rotating relative to the base and wherein the first lock element and the plunger define the respective cooperating lock geometries configured to, prior to activation, maintain the rotational lock between the plunger and the first lock element, the cooperating lock geometries being adapted to unlock to enable rotation between the plunger and the first lock element as the needle shield is moved towards the collapsed position.

6. The autoinjector as defined in claim **1**, wherein an external diameter of the plunger thread is larger than an internal diameter of a cylindrical section of the body of the cartridge.

7. The autoinjector as defined in claim **1**, wherein the plunger thread is accommodated at a proximal end of the plunger.

8. The autoinjector as defined in claim **1**, wherein the helical compression spring is arranged internally in a longitudinal bore of the plunger.

9. The autoinjector as defined in claim **1**, wherein the autoinjector irreplaceably accommodates the drug cartridge within the base and wherein the drug cartridge cannot be removed from the autoinjector without the use of tools.

10. The autoinjector as defined in claim **1**, wherein the force acting for causing rotation between the plunger and the base for releasing the plunger from the initial axial position is at least partly exerted by the actuating spring.

11. The autoinjector as defined in claim **10**, wherein the force acting for causing rotation between the plunger and the base for releasing the plunger and the base from the initial axial position is exclusively exerted by the actuating spring.

* * * * *